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Executive Summary of the

Participant Information Sheet/Consent Form - Adult

Standardised Treatment and Monitoring of Phage Therapy (STAMP)

[Local Chief Investigator]

You are invited to participate in the above research study because you have a bacterial infection that your doctor has determined would benefit from Phage Therapy and your doctor believes this could be a suitable treatment option for you. A detailed Information Statement about the study is attached and this is a summary of the essential information about the trial and where to find the relevant detailed information later in the Information Statement. You should read the Information Statement in full and discuss it with your family and medical practitioners before deciding to participate in this study. You may contact the study staff *[or provide a name]* to discuss or asks questions about the study on [phone number] or by email [email address].

This study aims to look at how Phage Therapy can be given to patients in a standardised way that will help better understand how the treatment affects you and other patients. If you agree you will receive a specific Phage Therapy product that is suitable for you as decided by your doctor. For a full description of the purpose and rationale for this research see pages 2-4.

Participation in this study is voluntary and refusal to participate or withdrawal from the study at a later stage will not affect the treatment you receive at *[department/hospital]*

If you decide to participate in this study you will be required to receive Phage Therapy as directed by your doctor. How long you will need to take the Phage Therapy for will be decided by your doctor by taking into consideration your medical history and the type of infection you have. During your treatment information about your background medical condition, your infection, the reason for Phage Therapy and your response to treatment will be collected. You will have blood and other samples (swabs, sputum samples etc.) collected. The schedule for study visits and a full list of all tests and procedures is on pages 3-4. After the study treatment has finished you will be followed by your primary doctor for at least 6 months and asked to complete a questionnaire after treatment.

The most common risks to participants from Phage Therapy is a brief inflammatory reaction (fever, headache, muscle aches). A full list of the side-effects from Phage Therapy and other risks associated with the study procedures are on page 6.

There is additional information about what information will be collected about you during the study, how that information will be used, and your privacy protected on pages 8-9. Your rights and additional regulatory information that we are obligated to provide on pages 9-10.

Please make sure you have completely understood what the study involves before you decide to participate.

Participant Information Sheet/Consent Form - Adult

Standardised Treatment and Monitoring of Phage therapy (STAMP)
Adult providing own consent

Title	Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy
Short Title	Standardised Treatment and Monitoring of Phage therapy (STAMP)
Project Sponsor	Western Sydney Local Health District
Coordinating Principal Investigator	Prof Jonathan Iredell
Site Principal Investigator	*[Site PI name]*
Location	*[Location]*

What does my participation involve?

1 Introduction

You are invited to take part in this research project because you have a bacterial infection that your doctor has determined would benefit from Phage Therapy. The research project is investigating the best way to provide Phage Therapy to patients, including how doctors should monitor the treatment.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your doctors.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2 What is the purpose of this research?

Phage Therapy is an experimental treatment. This means that it is not an approved treatment for bacterial infections in Australia. You will be receiving this treatment under the Special Access Scheme (SAS) of the Australian Therapeutic Goods Administration (TGA) which is sometimes referred to as "compassionate access". The decision to provide Phage Therapy to you and the specific phage product you will receive, has been decided by your doctors and is not part of this research project. This research will investigate how the treatment can be given to you in a standardised way so that we can better understand how the treatment affects you and other patients.

This research has been initiated by the study doctors, Professor Iredell, Associate Professor Steven Tong and Dr's Ameneh Khatami and Morgyn Warner. It has been funded by the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF) of Australia. It is being conducted by the Phage Australia Network of researchers (https://criticalinfection.com/phage-australia/).

3 What does participation in this research involve?

Once your doctor has determined that you may benefit from Phage Therapy, and a suitable phage product has been found, they will refer you to one of the study doctors. The study doctors will confirm that you are eligible to be enrolled in this research. This will include checking that all of the approvals that are required from Government agencies and other local hospital approvals that may be required have been obtained by your doctor. You will then be asked to sign a consent form before you can participate in the study.

The dose and duration of treatment with Phage Therapy, and the way in which it will be given to you (e.g. intravenously, by mouth, nebulised or topically) will be decided by one of the study doctors, after discussion with your primary (referring) doctor, taking into consideration your background medical conditions and the specific infection you have. Most patients will receive Phage Therapy for 2 weeks, given intravenously (through a drip, in a vein), and this will be provided to you in hospital. For some patients, if the Phage Therapy is required for a longer duration, this may be given to you in your home or an outpatient clinic. For other patients who only need Phage Therapy topically (e.g. onto a wound) or by a nebuliser (to be breathed into your lungs), this may also be given to you in your home or an outpatient clinic. In any circumstance, Phage Therapy will be given by qualified doctors and nurses, and prescribed to you in the same way as other medications.

For most people receiving 2 weeks of Phage Therapy intravenously (through a drip), this will be given once daily, in the morning for the first 2 days, and then twice a day (morning and evening) for the next 12 days. It is possible that you have once daily treatment for longer than 2 days during the 2 weeks, based on blood levels of the phage that will be measured throughout the treatment. Your doctors and nurses will also monitor your heart rate, breathing rate, blood pressure and temperature before and after each dose of phage.

Information regarding your background medical condition, your infection, the reason for Phage Therapy and your response to treatment will be collected in a standardised database. We will also collect blood and other samples that might be relevant for your specific infection (e.g. swabs or sputum samples). These samples will be collected at specified time-points before, during and after completion of the treatment to investigate how effective the treatment has been at clearing your infection, how it has affected your body in other ways, such as your kidneys and liver, and how your immune system has responded to the treatment.

For most people receiving 2 weeks of Phage Therapy intravenously (through a drip), blood samples will be collected the day before starting Phage Therapy (day 0), and again, 1, 3, 7, 10 and 14 days **after** your first dose (day 1). 4 weeks after your first dose of phage, which is about 2 weeks after your last dose of phage, you will have a follow-up visit with more blood tests and collection of relevant samples. On some days you will be asked to provide a blood sample 3 times: once before the morning dose of phage, and then 30-60 minutes, and 2-3 hours after the dose. This will help the study doctors understand how quickly phage is cleared from the body, and will also help determine whether you should receive once or twice daily treatment. The table below shows what days you will have blood tests compared to the first and last dose of phage you receive, and how many blood samples are needed each time.

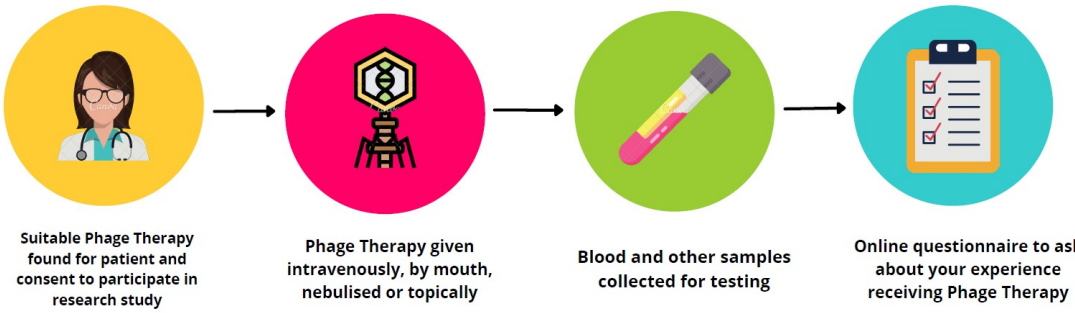
Day	**0**	**1**	**2**	**4**	**8**	**11**	**14**	**15**	**29**
Number of blood samples	x1	First dose of phage	x3	x3	x3	x3	Last dose of phage	x1	x1

Patients who do not receive any Phage Therapy through a drip in the vein, or by mouth, will have fewer blood tests. They will not have any blood tests on day 11, and on each day will only have a single set of blood samples taken.

Day	0	1	2	4	8	14	15	29
Number of blood samples	x1	First dose of phage	x1	x1	x1	Last dose of phage	x1	x1

Patients who have longer courses of Phage Therapy will continue to have blood tests to monitor their treatment every month. All blood samples will be collected by qualified health professionals (e.g. doctors, nurses or blood collectors).

Before starting Phage Therapy, at the end of the course and again 3 and 6 months after your treatment you will also be asked to complete an online questionnaire. This will ask you questions about your experience of the Phage Therapy and how it may have affected your quality of life. It will take 10 minutes to complete. Although we would like you to complete the entire questionnaire, you can skip any questions that you do not wish to answer.



For most patients, your main involvement in the study will be for 1 month. This includes the 2 weeks of Phage Therapy and the follow-up visit 2 weeks after completing Phage Therapy. During this time, in addition to the tests described above, you will be asked about any symptoms and health events that may have occurred so that study doctors can determine the safety of Phage Therapy. For some patients who are receiving longer courses of Phage Therapy, their involvement in the study will be determined by the duration of Phage Therapy that has been recommended for them. Once the Phage Therapy has finished, you will be followed up by your primary doctor for at least 6 months. The frequency of follow-up visits will be determined by your doctor, based on any underlying medical conditions. During this follow-up period you will also continue to receive invitations to complete the quality-of-life questionnaire at 3 and 6 months after your initial course of treatment.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

It is desirable that your local (family) doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions. It is

Khatami A, *et al. BMJ Open* 2022; 12:e065401. doi: 10.1136/bmjopen-2022-065401

important that administration of phage (including any dose changes) and all of the monitoring tests are done in a standardised way as written in the study protocol. It is also important that all of the information is collected in a standardised way so that the data from all participants in the study can be collated and analysed together. This includes answers you provide in the quality-of-life questionnaire. However, there will be no other restrictions on you with respect to diet, exercise or other activities, or other medications you may need. All of your other routine health care will continue as normal, and as determined by your doctor(s).

5 Other relevant information about the research project

This research is being conducted at multiple hospitals around Australia and will continue for 5 years. We are aiming to recruit 50-100 participants in the study during this time. At *[Location where the research will be conducted]* we expect around 2-3 participants to be recruited each year. The research is a collaboration between multiple hospitals, universities and research institutes working together.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *[Institution]*.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. If you choose not to participate in this research, your doctor(s) may still decide to offer you Phage Therapy but it may not be monitored in the way outlined in this research. This includes having access to some of the special tests that are not available in routine hospital or community labs. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your primary or local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include clearance of your infection, or stabilisation or improvement in your symptoms. In addition, your treatment will be overseen and monitored by a group of study doctors which include specialists in infectious diseases and Phage Therapy from around Australia and internationally. Importantly, the information that we collect in this research will help us and other researchers determine the best way to provide Phage Therapy to patients in the future. It may also help us be able to make Phage Therapy more widely available in Australia.

9 What are the possible risks and disadvantages of taking part?

Any medical treatment can cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

The specific phage product you will receive will be determined by your own doctor. This will be discussed with one of the study doctors, but this decision is not included in the research. Your doctor can provide you with specific information about the phage product you will receive, including where it has been sourced from and how it has been manufactured. Below is some general information about possible risks that might occur for patients receiving Phage Therapy.

Phage Therapy general information and risks
Phages are viruses that infect and kill bacterial cells, but they do not attack human cells. For this reason, phage therapy is considered very safe. It has been used for over 100 years to treat patients with bacterial infections. When phages are well purified to remove contaminants, they cause very few side effects. Only phage products that meet regulatory requirements regarding purification standards will be used in this research.

Sometimes a brief inflammatory reaction is seen after the initial doses of phage. This is mostly due to the phage attacking and killing the bacteria causing your infection. It is usually a good sign that the phages are doing their job but it may be uncomfortable for you. You may have a fever or feel unwell in other ways (chills, headache, muscle aches). Depending on the site of your bacterial infection, you may also experience pain at the site. Usually this inflammatory response is brief, lasting a few hours and can be managed with simple medication like paracetamol or ibuprofen. Rarely, there may be a severe reaction which may mean that further doses of phage are delayed or not given.

Other side effects that may occur during your treatment include abnormalities in results of tests of your liver or kidney function, blood cells and immune responses. If such abnormalities are seen, they will be monitored until they return to their baseline value. In our experience of treating patients in Australia, as well as reports from patients treated in other countries, these abnormalities in lab tests are usually not severe and resolve after a few weeks of stopping the Phage Therapy.

Unknown risks of Phage Therapy
There may also be side effects that we do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you experience. Sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you. Any side effects that may occur during your treatment will be managed or treated by the study doctors and your own doctors according to usual health care practice.

Risks of Phage Therapy of pregnancy and breastfeeding
Since phages do not attack human cells, we do not believe there are any additional risks of using Phage Therapy during pregnancy. However, if you are pregnant or breastfeeding, or you are trying to conceive a child and you have concerns about receiving Phage Therapy, please speak to your study doctors. You will not need to avoid pregnancy, breastfeeding, sperm or egg donation as a result of your participation in this research.

Risks of taking part in this research project
There are very few risks or disadvantages to taking part in this research because the study is mainly investigating how Phage Therapy should be given and monitored. As part of the research, you will be asked to provide blood and other samples at specific timepoints, and the phage will be given to you at specific times of the day, for most patients injected through an intravenous drip. Having a treatment injected or blood samples taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my test samples?

Most of the tests that will be performed to monitor your treatment are the same routine lab tests used by doctors to monitor infections. These tests will be performed at the usual labs where patient samples from *[Location where the research will be conducted]* are always processed. Once the testing is completed in these labs, the samples will be discarded and destroyed in the same way as other patient samples are handled by labs.

Some of the tests are specific to the Phage Therapy, including tests to determine the levels of phage in your blood, tests to look at how your immune system is responding to the Phage Therapy and tests that will investigate your microbiome (the collection of bacteria and other microorganisms, including viruses, which live in your body). Your blood and other samples (e.g. urine, sputum, faeces) for these tests may need to be sent to another lab in Australia that specialises in Phage Therapy. If this is the case, the samples will be sent in an anonymised way, using only a study code that will be assigned to you for the research project. No personal or identifiable information will be sent outside of *[Location where the research will be conducted]*. Only study doctors from *[Location where the research will be conducted]* and your clinical team will be able to re-identify these samples as yours, using your specific study code.

These tests are all required as part of your participation in the research. Once testing on these samples is completed, any remaining samples will be stored in the external lab in case further testing is required in the future (for this research project). We will also ask your permission to use these stored samples in other related research projects in the future, however this is optional. You can still take part in this research if you do not wish to have your samples used in other projects. Any leftover samples will be destroyed 15 years after the end of the study in the usual safe way that human samples are discarded and destroyed and according to law.

Genetic tests that will be performed in this research will be:
1) to investigate your microbiome which includes all of the bacteria, fungi and viruses that normally live in our bodies, and how these might change during Phage Therapy. This test will not look at any human genetic material, only at the genetic material of microorganisms.
2) to investigate the genes responsible for your immune system and how it responds to the Phage Therapy. This test will not look at any of your other genes so it is unlikely that it will identify any genetic disorders. There is a small chance that we may find that your immune system is not responding as well to infections as in other people. If that is the case, study doctors would let your doctor know the results so that they can discuss these with you and arrange any other investigations that might be needed.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Participating in this research project will not affect your ability to take other medications or treatments for your condition or for other reasons. However, it is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including

over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional information from or about you, although information already collected will be kept as part of the research to ensure that the results of the research can be measured properly and to comply with law. This information will only ever be used in an anonymised way and no personal or identifiable information about you will be used for research purposes. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell the study team before you join the research project.

14 Could this research project be stopped unexpectedly?

Although unlikely, this research project may be stopped unexpectedly for a variety of reasons, including unacceptable side effects or safety concerns.

15 What happens when the research project ends?

Once you have completed your course of Phage Therapy for your infection, no further ongoing access to Phage Therapy will be required. If further episodes of infection occur, including relapses or recurrence of the same infection, that require further courses of Phage Therapy, these future episodes will be treated as separate events and will be assessed for eligibility for you to be re-enrolled in the research project in the same way as for the initial course of treatment.

All other health care that may be required by you after the end of Phage Therapy will be according to routine practice and will be managed by your primary or local doctor.

After the project is completed in 5 years' time, the results of the research will be published in a scientific journal or may be presented at scientific meetings. A summary of publications and presentations will be made available for participants and the public on the Phage Australia website (https://criticalinfection.com/phage-australia/).

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal and health information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential and securely stored. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research (e.g. results of lab tests or scans). By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

All study information will be entered into a web-based database called REDCap. This is hosted by the University of Sydney and is protected so that only the study team can access the information. Within this database you would be assigned a study code. Your personal and identifiable information would only be available to the clinical team looking after you and the study team at *[Location where the research will be conducted]* so that they can discuss the best possible way to provide Phage Therapy to you, including any changes that might be needed in the dose of phage you are receiving. The rest of the research team would only have access to non-personal information through your anonymised study code.

Any of your blood or other samples that need to be sent to external labs will also only be identified with your study code and none of your personal or identifiable information will be sent outside of *[Location where the research will be conducted]*. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. All personal and identifiable information will be removed from the data when it is analysed and reported.

Paper documents, including copies of signed consent forms that include any personal or identifiable information will be stored in locked cupboards in offices at *[Location where the research will be conducted]*. All research data will be stored for 15 years after completion of the project, at which point all electronic documents with any identifiable information will be destroyed by permanent deletion and all paper files will be destroyed by shredding.

We will ask your permission to use your anonymised information in other related research projects in the future, however this is optional. You can still take part in this research if you do not wish to have your information used in other projects. Only anonymised information would be used for other future research projects and your personal or identifiable information will not be shared with anyone outside of the clinical team looking after you and the study team at *[Location where the research will be conducted]* without your permission.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, Western Sydney Local Health District, the institution relevant to this Participant Information Sheet, Sydney Children's Hospitals Network Human Research Ethics Committee, or as required by law. By signing the consent form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

In accordance with relevant Australian and *[Name of state/territory]* privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research has been funded by the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF) of Australia. It is being conducted by the Phage

Australia Network of researchers (https://criticalinfection.com/phage-australia/), including *[Name of local PI and relevant study staff]*.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Sydney Children's Hospitals Network.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor *[Name of local PI]* on *[phone number]* or any of the following people:

Clinical contact person

Name	During normal working hours: *[Site PI name]* After hours or if unable to contact *[Site PI name]*: Infectious diseases registrar or consultant on call
Position	*[Title/position/department of Site PI]*
Telephone	During normal working hours: *[Site PI contact number]* After hours: Infectious diseases registrar or consultant on call via *[Hospital switch/on call Phone number]*
Email	*[Site PI Email address]*

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Sydney Children's Hospital Network
HREC Executive Officer	Clare Bayram
Telephone	(02) 9845 3066
Email	SCHN-Ethics@health.nsw.gov.au

Consent Form - Adult providing own consent

Title	Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy
Short Title	Standardised Treatment and Monitoring of Phage therapy (STAMP)
Project Sponsor	Western Sydney Local Health District
Coordinating Principal Investigator	Prof Jonathan Iredell
Site Principal Investigator	*[Site PI name]*
Location	*[Location]*

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:
- This specific research project only
- This research project and other research that is closely related to this research project

Strike out one option above and initial next to your choice.

I consent to the storage and use of my de-identified (anonymous) information, as described in the relevant section of the Participant Information Sheet, for:
- This specific research project only
- This research project and other research that is closely related to this research project

Strike out one option above and initial next to your choice.

I agree to the use of my samples for genetic testing, as outlined in the relevant Section of the Participant Information Sheet.

Name of Participant (please print) _____

Signature _____ Date _____

If the person providing consent is unable to read, an impartial witness should be present during the entire informed consent discussion

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - Adult

Title	Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy
Short Title	Standardised Treatment and Monitoring of Phage therapy (STAMP)
Project Sponsor	Western Sydney Local Health District
Coordinating Principal Investigator	Prof Jonathan Iredell
Site Principal Investigator	*[Site PI name]*
Location	*[Location]*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

- I wish to withdraw from any further collection of samples and clinical data for this research
- I wish to withdraw from any further collection of samples but I am allowing continued collection of my clinical data for this research

Strike out one option above and initial next to your choice.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

Insert Header with institution's name or institution's letterhead

Executive Summary of the

Participant Information Sheet/Consent Form – Parent/Guardian

Standardised Treatment and Monitoring of Phage Therapy (STAMP)

[Local Chief Investigator]

Your child is invited to participate in the above research study because they have a bacterial infection that their doctor has determined would benefit from Phage Therapy and their doctor believes this could be a suitable treatment option for your child. A detailed Information Statement about the study is attached and this is a summary of the essential information about the trial and where to find the relevant detailed information later in the Information Statement. You should read the Information Statement in full and discuss it with your family and medical practitioners before deciding to consent to your child participating in this study. You may contact the study staff *[or provide a name]* to discuss or asks questions about the study on [phone number] or by email [email address].

This study aims to look at how Phage Therapy can be given to patients in a standardised way that will help better understand how the treatment affects them and other patients. If you agree your child will receive a specific Phage Therapy product that is suitable for them as decided by their doctor. For a full description of the purpose and rationale for this research see pages 2-4.

Participation in this study is voluntary and refusal to participate or withdrawal from the study at a later stage will not affect the treatment your child receives at *[department/hospital]*

If you decide to participate in this study your child will be required to receive Phage Therapy as directed by their doctor. How long they will need to take the Phage Therapy for will be decided by their doctor by taking into consideration medical history and the type of infection they have. During your treatment information about your child's background medical condition infection, the reason for Phage Therapy and their response to treatment will be collected. They will have blood and other samples (swabs, sputum samples etc.) collected. The schedule for study visits and a full list of all tests and procedures is on page 4. After the study treatment has finished your child will be followed by their primary doctor for at least 6 months and asked to complete a questionnaire after treatment.

The most common risks to participants from Phage Therapy is a brief inflammatory reaction (fever, headache, muscle aches). A full list of the side-effects from Phage Therapy and other risks associated with the study procedures are on page 6.

There is additional information about what information will be collected about your child during the study, how that information will be used, and their privacy protected on pages 8-9. Your rights and additional regulatory information that we are obligated to provide on pages 9-10.

Please make sure you have completely understood what the study involves before you decide to participate.

Participant Information Sheet/Consent Form – Parent/Guardian

Standardised Treatment and Monitoring of Phage therapy (STAMP)
Parent/Guardian consenting on behalf of participant

Title	Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy
Short Title	Standardised Treatment and Monitoring of Phage therapy (STAMP)
Project Sponsor	Western Sydney Local Health District
Coordinating Principal Investigator	Prof Jonathan Iredell
Site Principal Investigator	*[Site PI name]*
Location	*[Location]*

Part 1 What does my child's participation involve?

1 Introduction

Your child is invited to take part in this research project because they have a bacterial infection that their doctor has determined would benefit from Phage Therapy. The research project is investigating the best way to provide Phage Therapy to patients, including how doctors should monitor the treatment.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want your child to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not your child should take part, you might want to talk about it with a relative, friend or your doctors.

Participation in this research is voluntary. If you don't wish for your child to take part, they don't have to. They will receive the best possible care whether or not they take part.

If you decide you want your child to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent for your child to take part in the research project
• Consent for your child to have the tests and treatments that are described
• Consent to the use of your child's personal and health information as described.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2 What is the purpose of this research?

Phage Therapy is an experimental treatment. This means that it is not an approved treatment for bacterial infections in Australia. Your child will be receiving this treatment under the Special Access Scheme (SAS) of the Australian Therapeutic Goods Administration (TGA) which is sometimes referred to as "compassionate access". The decision to provide Phage Therapy to your child and the specific phage product they will receive, has been decided by their doctors and is not part of this research project. This research will investigate how the treatment can be

given to your child in a standardised way so that we can better understand how the treatment affects your child and other patients.

This research has been initiated by the study doctors, Professor Iredell, Associate Professor Steven Tong and Dr's Ameneh Khatami and Morgyn Warner. It has been funded by the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF) of Australia. It is being conducted by the Phage Australia Network of researchers (https://criticalinfection.com/phage-australia/).

3 What does participation in this research involve?

Once your doctor has determined that your child may benefit from Phage Therapy, and a suitable phage product has been found, they will refer your child to one of the study doctors. The study doctors will confirm that they are eligible to be enrolled in this research. This will include checking that all of the approvals that are required from Government agencies and other local hospital approvals that may be required have been obtained by their doctor. You will then be asked to sign a consent form before your child can participate in the study.

The dose and duration of treatment with Phage Therapy, and the way in which it will be given to your child (e.g. intravenously, by mouth, nebulised or topically) will be decided by one of the study doctors, after discussion with your child's primary (referring) doctor, taking into consideration your child's background medical conditions and the specific infection they have. Most patients will receive Phage Therapy for 2 weeks, given intravenously (through a drip, in a vein), and this will be provided to your child in hospital. For some patients, if the Phage Therapy is required for a longer duration, this may be given to your child in your home or an outpatient clinic. For other patients who only need Phage Therapy topically (e.g. onto a wound) or by a nebuliser (to be breathed into your lungs), this may also be given to your child in your home or an outpatient clinic. In any circumstance, Phage Therapy will be given by qualified doctors and nurses, and prescribed to your child in the same way as other medications.

For most people receiving 2 weeks of Phage Therapy intravenously (through a drip), this will be given once daily, in the morning for the first 2 days, and then twice a day (morning and evening) for the next 12 days. It is possible that your child may have once daily treatment for longer than 2 days during the 2 weeks, based on blood levels of the phage that will be measured throughout the treatment. Your child's doctors and nurses will also monitor their heart rate, breathing rate, blood pressure and temperature before and after each dose of phage.

Information regarding your child's background medical condition, their infection, the reason for Phage Therapy and their response to treatment will be collected in a standardised database. We will also collect blood and other samples that might be relevant for your child's specific infection (e.g. swabs or sputum samples). These samples will be collected at specified time-points before, during and after completion of the treatment to investigate how effective the treatment has been at clearing your child's infection, how it has affected their body in other ways, such as their kidneys and liver, and how their immune system has responded to the treatment.

For most people receiving 2 weeks of Phage Therapy intravenously (through a drip), blood samples will be collected the day before starting Phage Therapy (day 0), and again, 1, 3, 7, 10 and 14 days **after** their first dose (day 1). 4 weeks after your child's first dose of phage, which is about 2 weeks after their last dose of phage, your child will have a follow-up visit with more blood tests and collection of relevant samples. On some days your child will be asked to provide a blood sample 3 times: once before the morning dose of phage, and then 30-60 minutes, and 2-3 hours after the dose. This will help the study doctors understand how quickly phage is cleared from the body, and will also help determine whether they should receive once or twice daily treatment. The table below shows what days your child will have blood tests compared to the first and last dose of Phage Therapy they get, and how many blood samples are needed each time.

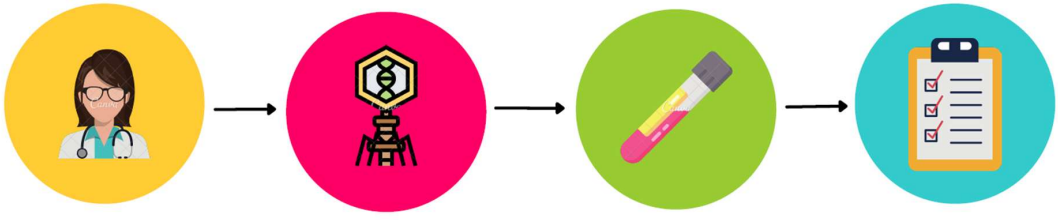
Day	**0**	**1**	**2**	**4**	**8**	**11**	**14**	**15**	**29**
Number of blood samples	x1	First dose of phage	x3	x3	x3	x3	Last dose of phage	x1	x1

Patients who do not receive any Phage Therapy through a drip in the vein, or by mouth, will have fewer blood tests. They will not have any blood tests on day 11, and on each day will only have a single set of blood samples taken.

Day	**0**	**1**	**2**	**4**	**8**	**14**	**15**	**29**
Number of blood samples	x1	First dose of phage	x1	x1	x1	Last dose of phage	x1	x1

Patients who have longer courses of Phage Therapy will continue to have blood tests to monitor their treatment every month. All blood samples will be collected by qualified health professionals (e.g. doctors, nurses or blood collectors).

Before starting Phage Therapy, at the end of the course and again 3 and 6 months after your child's treatment patients enrolled in the research who are at least 5 years old will also be asked to complete an online questionnaire. This will ask questions about their experience of the Phage Therapy and how it may have affected their quality of life. It will take 10 minutes to complete. We would ask that you help your child complete these questionnaires. Although we would like your child to complete the entire questionnaire, they and you can skip any questions that you do not wish to answer.



For most patients, their main involvement in the study will be for 1 month. This includes the 2 weeks of Phage Therapy and the follow-up visit 2 weeks after completing Phage Therapy. During this time, in addition to the tests described above, you and your child will be asked about any symptoms and health events that may have occurred so that study doctors can determine the safety of Phage Therapy. For some patients who are receiving longer courses of Phage Therapy, their involvement in the study will be determined by the duration of Phage Therapy that has been recommended for them. Once the Phage Therapy has finished, your child will be followed up by your child's primary doctor for at least 6 months. The frequency of follow-up visits will be determined by your child's doctor, based on any underlying medical conditions. During this follow-up period, if your child is at least 5 years old, they will also continue to receive invitations to complete the quality-of-life questionnaire at 3 and 6 months after their initial course of treatment.

There are no additional costs associated with participating in this research project, nor will you or your child be paid. All medication, tests and medical care required as part of the research project will be provided to your child free of charge.

It is desirable that your local (family) doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your child's participation in this research project.

4 What does my child have to do?

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions. It is important that administration of phage (including any dose changes) and all of the monitoring tests are done in a standardised way as written in the study protocol. It is also important that all of the information is collected in a standardised way so that the data from all participants in the study can be collated and analysed together. This includes answers you and your child provide in the quality-of-life questionnaires. However, there will be no other restrictions on your child with respect to diet, exercise or other activities, or other medications they may need. All of your child's other routine health care will continue as normal, and as determined by their doctor(s).

5 Other relevant information about the research project

This research is being conducted at multiple hospitals around Australia and will continue for 5 years. We are aiming to recruit 50-100 participants in the study during this time (including adults and children). At *[Location where the research will be conducted]* we expect around 2-3 participants to be recruited each year. The research is a collaboration between multiple hospitals, universities and research institutes working together.

6 Does my child have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for your child to take part, they do not have to. If you decide to take part and later change your mind, you are free to withdraw your child from the project at any stage.

If you do decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your child's routine treatment, you or your child's relationship with those treating your child or you or your child's relationship with *[Institution]*.

7 What are the alternatives to participation?

Your child does not have to take part in this research project to receive treatment at this hospital. If you choose not to participate in this research, your child's doctor(s) may still decide to offer them Phage Therapy but it may not be monitored in the way outlined in this research. This includes having access to some of the special tests that are not available in routine hospital or community labs. Your child's study doctor will discuss these options with you before you decide whether or not you want your child to take part in this research project. You can also discuss the options with your child's primary or local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that your child will receive any benefits from this research; however, possible benefits may include clearance of their infection, or stabilisation or improvement in their symptoms. In addition, your child's treatment will be overseen and monitored by a group of study doctors which include specialists in infectious diseases and Phage Therapy from around Australia and internationally. Importantly, the information that we collect in this research will help us and other researchers determine the best way to provide Phage Therapy to patients in the future. It may also help us be able to make Phage Therapy more widely available in Australia.

9 What are the possible risks and disadvantages of taking part?

Any medical treatment can cause side effects. Your child may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If your child has any of these side effects, or you are worried about them, talk with your child's study doctor. Your child's study doctor will also be looking out for side effects.

The specific phage product your child will receive will be determined by their own doctor. This will be discussed with one of the study doctors, but this decision is not included in the research. Your child's doctor can provide you with specific information about the phage product your child will receive, including where it has been sourced from and how it has been manufactured. Below is some general information about possible risks that might occur for patients receiving Phage Therapy.

Phage Therapy general information and risks

Phages are viruses that infect and kill bacterial cells, but they do not attack human cells. For this reason, phage therapy is considered very safe. It has been used for over 100 years to treat patients with bacterial infections. When phages are well purified to remove contaminants, they cause very few side effects. Only phage products that meet regulatory requirements regarding purification standards will be used in this research.

Sometimes a brief inflammatory reaction is seen after the initial doses of phage. This is mostly due to the phage attacking and killing the bacteria causing your child's infection. It is usually a good sign that the phages are doing their job but it may be uncomfortable for your child. They may have a fever or feel unwell in other ways (chills, headache, muscle aches). Depending on the site of your child's bacterial infection, they may also experience pain at the site. Usually this inflammatory response is brief, lasting a few hours and can be managed with simple medication like paracetamol or ibuprofen. Rarely, there may be a severe reaction which may mean that further doses of phage are delayed or not given.

Other side effects that may occur during your child's treatment include abnormalities in results of tests of their liver or kidney function, blood cells and immune responses. If such abnormalities are seen, they will be monitored until they return to their baseline value. In our experience of treating patients in Australia, as well as reports from patients treated in other countries, these abnormalities in lab tests are usually not severe and resolve after a few weeks of stopping the Phage Therapy.

Unknown risks of Phage Therapy

There may also be side effects that we do not expect or do not know about and that may be serious. Tell your child's study doctor immediately about any new or unusual symptoms that your child experiences. Sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your child's study doctor may need to stop your treatment. Your child's study doctor will discuss the best way of managing any side effects with you. Any side effects that may occur during your treatment will be managed or treated by the study doctors and your child's own doctors according to usual health care practice.

Risks of taking part in this research project

There are very few risks or disadvantages to taking part in this research because the study is mainly investigating how Phage Therapy should be given and monitored. As part of the research, your child will be asked to provide blood and other samples at specific timepoints, and the phage will be given to your child at specific times of the day, for most patients injected through an intravenous drip. Having a treatment injected or blood samples taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

If your child becomes upset or distressed as a result of their participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my child's test samples?

Most of the tests that will be performed to monitor your child's treatment are the same routine lab tests used by doctors to monitor infections. These tests will be performed at the usual labs where patient samples from *[Location where the research will be conducted]* are always processed. Once the testing is completed in these labs, the samples will be discarded and destroyed in the same way as other patient samples are handled by labs.

Some of the tests are specific to the Phage Therapy, including tests to determine the levels of phage in your child's blood, tests to look at how your child's immune system is responding to the Phage Therapy and tests that will investigate your child's microbiome (the collection of bacteria and other microorganisms, including viruses, which live in your body). Your child's blood and other samples (e.g. urine, sputum, faeces) for these tests may need to be sent to another lab in Australia that specialises in Phage Therapy. If this is the case, the samples will be sent in an anonymised way, using only a study code that will be assigned to your child for the research project. No personal or identifiable information will be sent outside of *[Location where the research will be conducted]*. Only study doctors from *[Location where the research will be conducted]* and your child's clinical team will be able to re-identify these samples as belonging to your child, using their specific study code.

These tests are all required as part of your child's participation in the research. Once testing on these samples is completed, any remaining samples will be stored in the external lab in case further testing is required in the future (for this research project). We will also ask your permission to use these stored samples in other related research projects in the future, however this is optional. Your child can still take part in this research if you do not wish to have their samples used in other projects. Any leftover samples will be destroyed 15 years after the end of the study in the usual safe way that human samples are discarded and destroyed and according to law.

Genetic tests that will be performed in this research will be:
1) to investigate your child's microbiome which includes all of the bacteria, fungi and viruses that normally live in our bodies, and how these might change during Phage Therapy. This test will not look at any human genetic material, only at the genetic material of microorganisms.
2) to investigate the genes responsible for your child's immune system and how it responds to the Phage Therapy. This test will not look at any of your child's other genes so it is unlikely that it will identify any genetic disorders. There is a small chance that we may find that your child's immune system is not responding as well to infections as in other people. If that is the case, study doctors would let your child's doctor know the results so that they can discuss these with you and arrange any other investigations that might be needed.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your child's study doctor will tell you about it and discuss with you whether you want your child to continue in the research project. If you decide to withdraw, your child's study doctor will make arrangements for your child's regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your child's study doctor might consider it to be in your child's best interests to withdraw them from the research project. If this happens, he/ she will explain the reasons and arrange for your child's regular health care to continue.

12 Can my child have other treatments during this research project?

Participating in this research project will not affect your child's ability to take other medications or treatments for their condition or for other reasons. However, it is important to tell your child's

study doctor and the study staff about any treatments or medications they may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your child's study doctor about any changes to these during your child's participation in the research project.

13 What if I withdraw my child from this research project?

If you decide to withdraw your child from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional information from or about your child, although information already collected will be kept as part of the research to ensure that the results of the research can be measured properly and to comply with law. This information will only ever be used in an anonymised way and no personal or identifiable information about your child will be used for research purposes. You should be aware that data collected by the sponsor up to the time you withdraw your child will form part of the research project results. If you do not want them to do this, you must tell the study team before your child joins the research project.

14 Could this research project be stopped unexpectedly?

Although unlikely, this research project may be stopped unexpectedly for a variety of reasons, including unacceptable side effects or safety concerns.

15 What happens when the research project ends?

Once your child has completed their course of Phage Therapy for their infection, no further ongoing access to Phage Therapy will be required. If further episodes of infection occur, including relapses or recurrence of the same infection, that require further courses of Phage Therapy, these future episodes will be treated as separate events and will be assessed for eligibility for your child to be re-enrolled in the research project, in the same way as for the initial course of treatment.

All other health care that may be required by your child after the end of Phage Therapy will be according to routine practice and will be managed by your child's primary or local doctor.

After the project is completed in 5 years' time, the results of the research will be published in a scientific journal or may be presented at scientific meetings. A summary of publications and presentations will be made available for participants and the public on the Phage Australia website (https://criticalinfection.com/phage-australia/).

Part 2 How is the research project being conducted?

16 What will happen to information about my child?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal and health information about your child for the research project. Any information obtained in connection with this research project that can identify your child will remain confidential and securely stored. Your child's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about your child may be obtained from their health records held at this and other health services for the purpose of this research (e.g. results of lab tests or scans). By signing the consent form you agree to the study team accessing health records if they are relevant to your child's participation in this research project.

All study information will be entered into a web-based database called REDCap. This is hosted by the University of Sydney and is protected so that only the study team can access the information. Within this database your child would be assigned a study code. Your child's personal and identifiable information would only be available to the clinical team looking after your child and the study team at *[Location where the research will be conducted]* so that they can discuss the best possible way to provide Phage Therapy to your child, including any changes that might be needed in the dose of phage they are receiving. The rest of the research team would only have access to non-personal information through your child's anonymised study code.

Any of your child's blood or other samples that need to be sent to external labs will also only be identified with their study code and none of your child's personal or identifiable information will be sent outside of *[Location where the research will be conducted]*. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that your child cannot be identified, except with your permission. All personal and identifiable information will be removed from the data when it is analysed and reported.

Paper documents, including copies of signed consent forms that include any personal or identifiable information will be stored in locked cupboards in offices at *[Location where the research will be conducted]*. All research data will be stored for 15 years after completion of the project, at which point all electronic documents with any identifiable information will be destroyed by permanent deletion and all paper files will be destroyed by shredding.

We will ask your permission to use your child's anonymised information in other related research projects in the future, however this is optional. Your child can still take part in this research if you do not wish to have their information used in other projects. Only anonymised information would be used for other future research projects and your child's personal or identifiable information will not be shared with anyone outside of the clinical team looking after your child and the study team at *[Location where the research will be conducted]* without your permission.

Your child's health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, Western Sydney Local Health District, the institution relevant to this Participant Information Sheet, Sydney Children's Hospitals Network Human Research Ethics Committee, or as required by law. By signing the consent form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

In accordance with relevant Australian and *[Name of state/territory]* privacy and other relevant laws, you have the right to request access to your child's information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your child's information.

17 Complaints and Compensation

If your child suffers any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If your child is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research has been funded by the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF) of Australia. It is being conducted by the Phage Australia Network of researchers (https://criticalinfection.com/phage-australia/), including *[Name of local PI and relevant study staff]*.

No member of the research team will receive a personal financial benefit from your child's involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Sydney Children's Hospitals Network.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if your child has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor *[Name of local PI]* on *[phone number]* or any of the following people:

Clinical contact person

Name	During normal working hours: *[Site PI name]* After hours or if unable to contact *[Site PI name]*: Infectious diseases registrar or consultant on call
Position	*[Title/position/department of Site PI]*
Telephone	During normal working hours: *[Site PI contact number]* After hours: Infectious diseases registrar or consultant on call via *[Hospital switch/on call Phone number]*
Email	*[Site PI Email address]*

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Sydney Children's Hospital Network
HREC Executive Officer	Clare Bayram
Telephone	(02) 9845 3066
Email	SCHN-Ethics@health.nsw.gov.au

Consent Form – Parent/Guardian

Title	Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy
Short Title	Standardised Treatment and Monitoring of Phage therapy (STAMP)
Project Sponsor	Western Sydney Local Health District
Coordinating Principal Investigator	Prof Jonathan Iredell
Site Principal Investigator	*[Site PI name]*
Location	*[Location]*

Declaration by Parent/Guardian

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my child's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning my child's disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to have my child participate in this research project as described and understand that I am free to withdraw my child at any time during the study without affecting their future health care.

I understand that I will be given a signed copy of this document to keep.

I consent to the storage and use of blood and tissue samples taken from my child for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project only
- This research project and other research that is closely related to this research project

Strike out one option above and initial next to your choice.

I consent to the storage and use of my child's de-identified (anonymous) information, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project only
- This research project and other research that is closely related to this research project

Strike out one option above and initial next to your choice.

I agree to the use of my child's samples for genetic testing, as outlined in the relevant Section of the Participant Information Sheet.

Name of Child (please print)	
Signature of Child	Date
Name of Parent/Guardian (please print)	

Signature of Parent/Guardian _____ Date _____

If the person providing consent is unable to read, an impartial witness should be present during the entire informed consent discussion

Name of Witness* to Parent/Guardian's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the parent/guardian has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation – Parent/Guardian

Title	Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy
Short Title	Standardised Treatment and Monitoring of Phage therapy (STAMP)
Project Sponsor	Western Sydney Local Health District
Coordinating Principal Investigator	Prof Jonathan Iredell
Site Principal Investigator	*[Site PI name]*
Location	*[Location]*

Declaration by Parent/Guardian

I wish to withdraw my child from participation in the above research project and understand that such withdrawal will not affect my child's routine treatment, our relationship with those treating my child or our relationship with *[Institution]*.

- I wish to withdraw my child from any further collection of samples and clinical data for this research
- I wish to withdraw my child from any further collection of samples but I am allowing continued collection of my child's clinical data for this research

Strike out one option above and initial next to your choice.

Name of Child (please print) _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date_____

In the event that the parent/guardian's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the parent/guardian has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

Insert Header with institution's name or institution's letterhead

Executive Summary of the
Participant Information Sheet/Consent Form – Person Responsible

Standardised Treatment and Monitoring of Phage Therapy (STAMP)

[Local Chief Investigator]

The participant is invited to participate in the above research study because they have a bacterial infection that their doctor has determined would benefit from Phage Therapy and their doctor believes this could be a suitable treatment option. A detailed Information Statement about the study is attached and this is a summary of the essential information about the trial and where to find the relevant detailed information later in the Information Statement. You should read the Information Statement in full and discuss it with your family and medical practitioners before deciding to agree to participation of the person you are responsible for in this study. You may contact the study staff *[or provide a name]* to discuss or asks questions about the study on [phone number] or by email [email address].

This study aims to look at how Phage Therapy can be given to patients in a standardised way that will help better understand how the treatment affects them and other patients. If you agree, the person you are responsible for will receive a specific Phage Therapy product that is suitable for them as decided by their doctor. For a full description of the purpose and rationale for this research see pages 2-4.

Participation in this study is voluntary and refusal to participate or withdrawal from the study at a later stage will not affect the treatment they receive at *[department/hospital]*

If you decide the person you are responsible for should participate in this study they will be required to receive Phage Therapy as directed by their doctor. How long they will need to take the Phage Therapy for will be decided by their doctor, taking into consideration medical history and the type of infection they have. During treatment information about the participant's background medical condition, infection, the reason for Phage Therapy and response to treatment will be collected. They will have blood and other samples (swabs, sputum samples etc.) collected. The schedule for study visits and a full list of all tests and procedures is on page 4. After the study treatment has finished they will be followed by their primary doctor for at least 6 months and asked to complete a questionnaire after treatment.

The most common risks to participants from Phage Therapy is a brief inflammatory reaction (fever, headache, muscle aches). A full list of the side-effects from Phage Therapy and other risks associated with the study procedures are on page 6.

There is additional information about what information will be collected about the participant during the study, how that information will be used, and their privacy protected on pages 8-9. Their rights and additional regulatory information that we are obligated to provide on pages 9-10.

Please make sure you have completely understood what the study involves before you decide to consent to participation on behalf of the person you are responsible for.

Participant Information Sheet/Consent Form – Person Responsible

Standardised Treatment and Monitoring of Phage therapy (STAMP)
Person responsible consenting on behalf of participant

Title	Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy
Short Title	Standardised Treatment and Monitoring of Phage therapy (STAMP)
Project Sponsor	Western Sydney Local Health District
Coordinating Principal Investigator	Prof Jonathan Iredell
Site Principal Investigator	*[Site PI name]*
Location	*[Location]*

Part 1 What does participation involve?

1 Introduction

The participant is invited to take part in this research project because they have a bacterial infection that their doctor has determined would benefit from Phage Therapy. The research project is investigating the best way to provide Phage Therapy to patients, including how doctors should monitor the treatment.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want the participant to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not the participant should take part, you might want to talk about it with a relative, friend or your doctors.

Participation in this research is voluntary. If you don't wish for the participant to take part, they don't have to. They will receive the best possible care whether or not they take part.

If you decide you want the participant to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent for the participant to take part in the research project
• Consent for the participant to have the tests and treatments that are described
• Consent to the use of the participant's personal and health information as described.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2 What is the purpose of this research?

Phage Therapy is an experimental treatment. This means that it is not an approved treatment for bacterial infections in Australia. The participant will be receiving this treatment under the Special Access Scheme (SAS) of the Australian Therapeutic Goods Administration (TGA) which is sometimes referred to as "compassionate access". The decision to provide Phage Therapy to the participant and the specific phage product they will receive, has been decided by their

doctors and is not part of this research project. This research will investigate how the treatment can be given to the participant in a standardised way so that we can better understand how the treatment affects the participant and other patients.

This research has been initiated by the study doctors, Professor Iredell, Associate Professor Steven Tong and Dr's Ameneh Khatami and Morgyn Warner. It has been funded by the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF) of Australia. It is being conducted by the Phage Australia Network of researchers (https://criticalinfection.com/phage-australia/).

3 What does participation in this research involve?

Once your doctor has determined that the participant may benefit from Phage Therapy, and a suitable phage product has been found, they will refer the participant to one of the study doctors. The study doctors will confirm that they are eligible to be enrolled in this research. This will include checking that all of the approvals that are required from Government agencies and other local hospital approvals that may be required have been obtained by their doctor. You will then be asked to sign a consent form before the participant can take part in the study.

The dose and duration of treatment with Phage Therapy, and the way in which it will be given to the participant (e.g. intravenously, by mouth, nebulised or topically) will be decided by one of the study doctors, after discussion with the participant's primary (referring) doctor, taking into consideration the participant's background medical conditions and the specific infection they have. Most patients will receive Phage Therapy for 2 weeks, given intravenously (through a drip, in a vein), and this will be provided to the participant in hospital. For some patients, if the Phage Therapy is required for a longer duration, this may be given to the participant in their home or an outpatient clinic. For other patients who only need Phage Therapy topically (e.g. onto a wound) or by a nebuliser (to be breathed into your lungs), this may also be given to the participant in their home or an outpatient clinic. In any circumstance, Phage Therapy will be given by qualified doctors and nurses, and prescribed to the participant in the same way as other medications.

For most people receiving 2 weeks of Phage Therapy intravenously (through a drip), this will be given once daily, in the morning for the first 2 days, and then twice a day (morning and evening) for the next 12 days. It is possible that the participant may have once daily treatment for longer than 2 days during the 2 weeks, based on blood levels of the phage that will be measured throughout the treatment. The participant's doctors and nurses will also monitor their heart rate, breathing rate, blood pressure and temperature before and after each dose of phage.

Information regarding the participant's background medical condition, their infection, the reason for Phage Therapy and their response to treatment will be collected in a standardised database. We will also collect blood and other samples that might be relevant for the participant's specific infection (e.g. swabs or sputum samples). These samples will be collected at specified time-points before, during and after completion of the treatment to investigate how effective the treatment has been at clearing the participant's infection, how it has affected their body in other ways, such as their kidneys and liver, and how their immune system has responded to the treatment.

For most people receiving 2 weeks of Phage Therapy intravenously (through a drip), blood samples will be collected the day before starting Phage Therapy (day 0), and again, 1, 3, 7, 10 and 14 days **after** their first dose (day 1). 4 weeks after the participant's first dose of phage, which is about 2 weeks after their last dose of phage, the participant will have a follow-up visit with more blood tests and collection of relevant samples. On some days the participant will be asked to provide a blood sample 3 times: once before the morning dose of phage, and then 30-60 minutes, and 2-3 hours after the dose. This will help the study doctors understand how quickly phage is cleared from the body, and will also help determine whether they should receive once or twice daily treatment. The table below shows what days the participant will have blood tests compared to the first and last dose of phage they receive, and how many blood samples are needed each time.

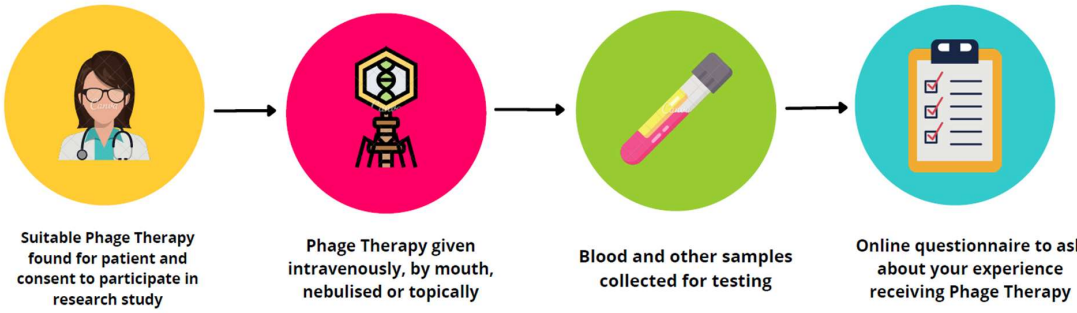
Day	0	1	2	4	8	11	14	15	29
Number of blood samples	x1	First dose of phage	x3	x3	x3	x3	Last dose of phage	x1	x1

Patients who do not receive any Phage Therapy through a drip in the vein, or by mouth, will have fewer blood tests. They will not have any blood tests on day 11, and on each day will only have a single set of blood samples taken.

Day	0	1	2	4	8	14	15	29
Number of blood samples	x1	First dose of phage	x1	x1	x1	Last dose of phage	x1	x1

Patients who have longer courses of Phage Therapy will continue to have blood tests to monitor their treatment every month. All blood samples will be collected by qualified health professionals (e.g. doctors, nurses or blood collectors).

Before starting Phage Therapy, at the end of the course and again 3 and 6 months after the participant's treatment they will also be asked to complete an online questionnaire. This will ask questions about their experience of the Phage Therapy and how it may have affected their quality of life. It will take 10 minutes to complete. We would ask that you help the participant complete these questionnaires. Although we would like the participant to complete the entire questionnaire, they and you can skip any questions that you do not wish to answer.



For most patients, their main involvement in the study will be for 1 month. This includes the 2 weeks of Phage Therapy and the follow-up visit 2 weeks after completing Phage Therapy. During this time, in addition to the tests described above, you and the participant will be asked about any symptoms and health events that may have occurred so that study doctors can determine the safety of Phage Therapy. For some patients who are receiving longer courses of Phage Therapy, their involvement in the study will be determined by the duration of Phage Therapy that has been recommended for them. Once the Phage Therapy has finished, the participant will be followed up by the participant's primary doctor for at least 6 months. The frequency of follow-up visits will be determined by the participant's doctor, based on any underlying medical conditions. During this follow-up period, they will also continue to receive invitations to complete the quality-of-life questionnaire at 3 and 6 months after their initial course of treatment.

There are no additional costs associated with participating in this research project, nor will you or the participant be paid. All medication, tests and medical care required as part of the research project will be provided to the participant free of charge.

It is desirable that your local (family) doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of the participant's participation in this research project.

4 What does the participant have to do?

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions. It is important that administration of phage (including any dose changes) and all of the monitoring tests are done in a standardised way as written in the study protocol. It is also important that all of the information is collected in a standardised way so that the data from all participants in the study can be collated and analysed together. This includes answers you and the participant provide in the quality-of-life questionnaires. However, there will be no other restrictions on the participant with respect to diet, exercise or other activities, or other medications they may need. All of the participant's other routine health care will continue as normal, and as determined by their doctor(s).

5 Other relevant information about the research project

This research is being conducted at multiple hospitals around Australia and will continue for 5 years. We are aiming to recruit 50-100 participants in the study during this time. At *[Location where the research will be conducted]* we expect around 2-3 participants to be recruited each year. The research is a collaboration between multiple hospitals, universities and research institutes working together.

6 Does the participant have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for the participant to take part, they do not have to. If you decide to take part and later change your mind, you are free to withdraw the participant from the project at any stage.

If you do decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect the participant's routine treatment, you or the participant's relationship with those treating the participant or you or the participant's relationship with *[Institution]*.

7 What are the alternatives to participation?

The participant does not have to take part in this research project to receive treatment at this hospital. If you choose not to participate in this research, the participant's doctor(s) may still decide to offer them Phage Therapy but it may not be monitored in the way outlined in this research. This includes having access to some of the special tests that are not available in routine hospital or community labs. The study doctor will discuss these options with you before you decide whether or not you want the participant to take part in this research project. You can also discuss the options with the participant's primary or local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that the participant will receive any benefits from this research; however, possible benefits may include clearance of their infection, or stabilisation or improvement in their symptoms. In addition, the participant's treatment will be overseen and monitored by a group of study doctors which include specialists in infectious diseases and Phage Therapy from around Australia and internationally. Importantly, the information that we collect in this research will help us and other researchers determine the best way to provide Phage Therapy to patients in the future. It may also help us be able to make Phage Therapy more widely available in Australia.

9 What are the possible risks and disadvantages of taking part?

Any medical treatment can cause side effects. The participant may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If the participant has any of these side effects, or you are worried about them, talk with the study doctor. The study doctor will also be looking out for side effects.

The specific phage product the participant will receive will be determined by their own doctor. This will be discussed with one of the study doctors, but this decision is not included in the research. The participant's doctor can provide you with specific information about the phage product the participant will receive, including where it has been sourced from and how it has been manufactured. Below is some general information about possible risks that might occur for patients receiving Phage Therapy.

Phage Therapy general information and risks
Phages are viruses that infect and kill bacterial cells, but they do not attack human cells. For this reason, phage therapy is considered very safe. It has been used for over 100 years to treat patients with bacterial infections. When phages are well purified to remove contaminants, they cause very few side effects. Only phage products that meet regulatory requirements regarding purification standards will be used in this research.

Sometimes a brief inflammatory reaction is seen after the initial doses of phage. This is mostly due to the phage attacking and killing the bacteria causing the participant's infection. It is usually a good sign that the phages are doing their job but it may be uncomfortable for the participant. They may have a fever or feel unwell in other ways (chills, headache, muscle aches). Depending on the site of the participant's bacterial infection, they may also experience pain at the site. Usually this inflammatory response is brief, lasting a few hours and can be managed with simple medication like paracetamol or ibuprofen. Rarely, there may be a severe reaction which may mean that further doses of phage are delayed or not given.

Other side effects that may occur during the participant's treatment include abnormalities in results of tests of their liver or kidney function, blood cells and immune responses. If such abnormalities are seen, they will be monitored until they return to their baseline value. In our experience of treating patients in Australia, as well as reports from patients treated in other countries, these abnormalities in lab tests are usually not severe and resolve after a few weeks of stopping the Phage Therapy.

Unknown risks of Phage Therapy
There may also be side effects that we do not expect or do not know about and that may be serious. Tell the study doctor immediately about any new or unusual symptoms that the participant experiences. Sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, the study doctor may need to stop your treatment. The study doctor will discuss the best way of managing any side effects with you. Any side effects that may occur during your treatment will be managed or treated by the study doctors and the participant's own doctors according to usual health care practice.

Risks of taking part in this research project
There are very few risks or disadvantages to taking part in this research because the study is mainly investigating how Phage Therapy should be given and monitored. As part of the research, the participant will be asked to provide blood and other samples at specific timepoints, and the phage will be given to the participant at specific times of the day, for most patients injected through an intravenous drip. Having a treatment injected or blood samples taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

If the participant becomes upset or distressed as a result of their participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any

counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to the participant's test samples?

Most of the tests that will be performed to monitor the participant's treatment are the same routine lab tests used by doctors to monitor infections. These tests will be performed at the usual labs where patient samples from *[Location where the research will be conducted]* are always processed. Once the testing is completed in these labs, the samples will be discarded and destroyed in the same way as other patient samples are handled by labs.

Some of the tests are specific to the Phage Therapy, including tests to determine the levels of phage in the participant's blood, tests to look at how the participant's immune system is responding to the Phage Therapy and tests that will investigate the participant's microbiome (the collection of bacteria and other microorganisms, including viruses, which live in your body). The participant's blood and other samples (e.g. urine, sputum, faeces) for these tests may need to be sent to another lab in Australia that specialises in Phage Therapy. If this is the case, the samples will be sent in an anonymised way, using only a study code that will be assigned to the participant for the research project. No personal or identifiable information will be sent outside of *[Location where the research will be conducted]*. Only study doctors from *[Location where the research will be conducted]* and the participant's clinical team will be able to re-identify these samples as belonging to the participant, using their specific study code.

These tests are all required for the participant to take part in the research. Once testing on these samples is completed, any remaining samples will be stored in the external lab in case further testing is required in the future (for this research project). We will also ask your permission to use these stored samples in other related research projects in the future, however this is optional. The participant can still take part in this research if you do not wish to have their samples used in other projects. Any leftover samples will be destroyed 15 years after the end of the study in the usual safe way that human samples are discarded and destroyed and according to law.

Genetic tests that will be performed in this research will be:
1) to investigate the participant's microbiome which includes all of the bacteria, fungi and viruses that normally live in our bodies, and how these might change during Phage Therapy. This test will not look at any human genetic material, only at the genetic material of microorganisms.
2) to investigate the genes responsible for the participant's immune system and how it responds to the Phage Therapy. This test will not look at any of the participant's other genes so it is unlikely that it will identify any genetic disorders. There is a small chance that we may find that the participant's immune system is not responding as well to infections as in other people. If that is the case, study doctors would let the participant's doctor know the results so that they can discuss these with you and arrange any other investigations that might be needed.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the study doctor will tell you about it and discuss with you whether you want the participant to continue in the research project. If you decide to withdraw, the study doctor will make arrangements for the participant's regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, the study doctor might consider it to be in the participant's best interests to withdraw them from the research project. If this happens, he/ she will explain the reasons and arrange for the participant's regular health care to continue.

12 Can the participant have other treatments during this research project?

Participating in this research project will not affect the participant's ability to take other medications or treatments for their condition or for other reasons. However, it is important to tell the study doctor and the study staff about any treatments or medications they may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the study doctor about any changes to these while the participant is taking part in the research project.

13 What if I withdraw the participant from this research project?

If you decide to withdraw the participant from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional information from or about the participant, although information already collected will be kept as part of the research to ensure that the results of the research can be measured properly and to comply with law. This information will only ever be used in an anonymised way and no personal or identifiable information about the participant will be used for research purposes. You should be aware that data collected by the sponsor up to the time you withdraw the participant will form part of the research project results. If you do not want them to do this, you must tell the study team before the participant joins the research project.

14 Could this research project be stopped unexpectedly?

Although unlikely, this research project may be stopped unexpectedly for a variety of reasons, including unacceptable side effects or safety concerns.

15 What happens when the research project ends?

Once the participant has completed their course of Phage Therapy for their infection, no further ongoing access to Phage Therapy will be required. If further episodes of infection occur, including relapses or recurrence of the same infection, that require further courses of Phage Therapy, these future episodes will be treated as separate events and will be assessed for eligibility for the participant to be re-enrolled in the research project, in the same way as for the initial course of treatment.

All other health care that may be required by the participant after the end of Phage Therapy will be according to routine practice and will be managed by the participant's primary or local doctor.

After the project is completed in 5 years' time, the results of the research will be published in a scientific journal or may be presented at scientific meetings. A summary of publications and presentations will be made available for participants and the public on the Phage Australia website (https://criticalinfection.com/phage-australia/).

Part 2 How is the research project being conducted?

16 What will happen to information about the participant?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal and health information about the participant for the research project. Any information obtained in connection with this research project that can identify the participant will remain confidential and securely stored. The participant's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about the participant may be obtained from their health records held at this and other health services for the purpose of this research (e.g. results of lab tests or scans). By signing the consent form you agree to the study team accessing health records if they are relevant to the participant taking part in this research project.

All study information will be entered into a web-based database called REDCap. This is hosted by the University of Sydney and is protected so that only the study team can access the information. Within this database the participant would be assigned a study code. The participant's personal and identifiable information would only be available to the clinical team looking after the participant and the study team at *[Location where the research will be conducted]* so that they can discuss the best possible way to provide Phage Therapy to the participant, including any changes that might be needed in the dose of phage they are receiving. The rest of the research team would only have access to non-personal information through the participant's anonymised study code.

Any of the participant's blood or other samples that need to be sent to external labs will also only be identified with their study code and none of the participant's personal or identifiable information will be sent outside of *[Location where the research will be conducted]*. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your permission. All personal and identifiable information will be removed from the data when it is analysed and reported.

Paper documents, including copies of signed consent forms that include any personal or identifiable information will be stored in locked cupboards in offices at *[Location where the research will be conducted]*. All research data will be stored for 15 years after completion of the project, at which point all electronic documents with any identifiable information will be destroyed by permanent deletion and all paper files will be destroyed by shredding.

We will ask your permission to use the participant's anonymised information in other related research projects in the future, however this is optional. The participant can still take part in this research if you do not wish to have their information used in other projects. Only anonymised information would be used for other future research projects and the participant's personal or identifiable information will not be shared with anyone outside of the clinical team looking after the participant and the study team at *[Location where the research will be conducted]* without your permission.

The participant's health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, Western Sydney Local Health District, the institution relevant to this Participant Information Sheet, Sydney Children's Hospitals Network Human Research Ethics Committee, or as required by law. By signing the consent form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

In accordance with relevant Australian and *[Name of state/territory]* privacy and other relevant laws, you have the right to request access to the participant's information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access the participant's information.

17 Complaints and Compensation

If the participant suffers any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If the participant is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research has been funded by the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF) of Australia. It is being conducted by the Phage Australia Network of researchers (https://criticalinfection.com/phage-australia/), including *[Name of local PI and relevant study staff]*.

No member of the research team will receive a personal financial benefit from the participant's involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Sydney Children's Hospitals Network.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor *[Name of local PI]* on *[phone number]* or any of the following people:

Clinical contact person

Name	During normal working hours: *[Site PI name]* After hours or if unable to contact *[Site PI name]*: Infectious diseases registrar or consultant on call
Position	*[Title/position/department of Site PI]*
Telephone	During normal working hours: *[Site PI contact number]* After hours: Infectious diseases registrar or consultant on call via *[Hospital switch/on call Phone number]*
Email	*[Site PI Email address]*

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Sydney Children's Hospital Network
HREC Executive Officer	Clare Bayram
Telephone	(02) 9845 3066
Email	SCHN-Ethics@health.nsw.gov.au

Consent Form – Person Responsible

Title	Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy
Short Title	Standardised Treatment and Monitoring of Phage therapy (STAMP)
Project Sponsor	Western Sydney Local Health District
Coordinating Principal Investigator	Prof Jonathan Iredell
Site Principal Investigator	*[Site PI name]*
Location	*[Location]*

Declaration by Person Responsible

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for the participant's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning the participant's disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to the participant taking part in this research project as described and understand that I am free to withdraw the participant at any time during the study without affecting their future health care.

I understand that I will be given a signed copy of this document to keep.

I consent to the storage and use of blood and tissue samples taken from the participant for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project only
- This research project and other research that is closely related to this research project

Strike out one option above and initial next to your choice.

I consent to the storage and use of the participant's de-identified (anonymous) information, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project only
- This research project and other research that is closely related to this research project

Strike out one option above and initial next to your choice.

I agree to the use of the participant's samples for genetic testing, as outlined in the relevant Section of the Participant Information Sheet.

Name of Participant (please print) _____

Name of Person Responsible (please print) _____

Signature of Person Responsible _____ Date_____

If the person providing consent is unable to read, an impartial witness should be present during the entire informed consent discussion

Name of Witness* to Person Responsible's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the Person Responsible has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation – Person Responsible

Title	Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy
Short Title	Standardised Treatment and Monitoring of Phage therapy (STAMP)
Project Sponsor	Western Sydney Local Health District
Coordinating Principal Investigator	Prof Jonathan Iredell
Site Principal Investigator	*[Site PI name]*
Location	*[Location]*

Declaration by Person Responsible

I wish to withdraw the participant from participation in the above research project and understand that such withdrawal will not affect the participant's routine treatment, our relationship with those treating the participant or our relationship with *[Institution]*.

- I wish to withdraw the participant from any further collection of samples and clinical data for this research
- I wish to withdraw the participant from any further collection of samples but I am allowing continued collection of the participant's clinical data for this research

Strike out one option above and initial next to your choice.

Name of Participant (please print) _____

Name of Person Responsible (please print) _____

Signature of Person Responsible _____ Date _____

In the event that the person responsible's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the Person Responsible has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

Insert Header with institution's name or institution's letterhead

Participant Information Sheet – Young Person

Standardised Treatment and Monitoring of Phage therapy (STAMP)

Title	Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy
Short Title	Standardised Treatment and Monitoring of Phage therapy (STAMP)
Project Sponsor	Western Sydney Local Health District
Coordinating Principal Investigator	Prof Jonathan Iredell
Site Principal Investigator	*[Site PI name]*
Location	*[Location]*

What does my participation involve?

1 Introduction

You are invited to take part in this research project because you have an infection that your doctor thinks would benefit from Phage Therapy. The research project is investigating the best way to provide Phage Therapy to patients, including how doctors should monitor the treatment.

This Participant Information Sheet tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you should talk about it with your parents or guardians and your doctor.

Participation in this research is voluntary. If you don't want to take part, you don't have to. You will receive the best possible care whether or not you take part.

2 What is the purpose of this research?

Phage Therapy is an experimental treatment. This means that it is not an approved treatment for infections in Australia. The decision to give you Phage Therapy and the specific phage product you will get, has been decided by your doctor and is not part of this research project. This research will look at **how** the treatment should be given to you so that we can better understand how it affects you and other patients like you.

3 What does participation in this research involve?

Once your doctor has decided that Phage Therapy might be good for you, and a suitable phage product has been found for you, they will refer you to one of the study doctors. The study doctors will check that it is o.k. to enrol you in this research. Your parent or guardian will then be asked to sign a consent form before you can take part in the study.

How much of the phage you get, and for how long, and the way in which it will be given to you (through a drip in your vein, by mouth, breathed in or another way) will be decided by one of the

study doctors, after talking with your doctor. They will make these decisions by thinking about your medical conditions and the specific infection you have. Most patients will get Phage Therapy for 2 weeks in hospital, given through a drip in a vein. For some patients, if the Phage Therapy is needed for longer, this might be given to you in your home or an outpatient clinic. Phage Therapy will always be given by doctors and nurses, and prescribed to you in the same way as other medications.

For most people who get 2 weeks of Phage Therapy through a drip, this will be given only once a day, in the morning for the first 2 days, and then twice a day (morning and evening) for the next 12 days. It is possible that you have once daily treatment for longer than 2 days during the 2 weeks, based on levels of the phage in your blood that will be measured throughout the treatment. Your doctors and nurses will also monitor your heart rate, breathing rate, blood pressure and temperature before and after each dose of phage.

Information regarding your medical condition, your infection, the reason why you are getting Phage Therapy and how your body responds to the treatment will be collected in a database. We will also collect blood and other samples that might be needed for your specific infection (such as swabs or sputum samples). These samples will be collected at specific time-points before, during and after completion of the treatment to try to understand how good the treatment has been at clearing your infection, how it has affected your body in other ways, such as your kidneys and liver, and how your immune system has responded to the treatment.

For most people who get 2 weeks of Phage Therapy through a drip, blood samples will be collected the day before starting Phage Therapy (day 0), and again, 1, 3, 7, 10 and 14 days **after** your first dose (day 1). 4 weeks after your first dose of phage, which is about 2 weeks after your last dose of phage, you will have a follow-up visit with more blood tests. On some of these days, you will be asked to give a blood sample 3 times: once before the morning dose of phage, and then 30-60 minutes, and 2-3 hours after the dose. This will help the study doctors understand how quickly the phage leaves your body, and will also help work out if you should get once or twice daily treatment. The table below shows what days you will have blood tests compared to the first and last dose of phage you get, and how many blood samples are needed each time.

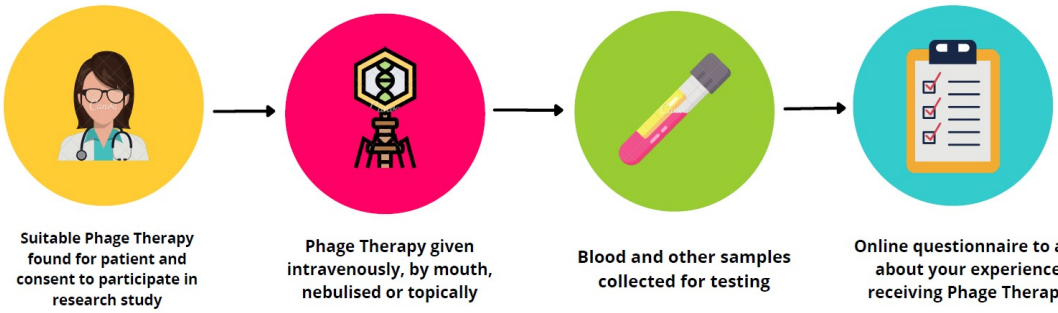
Day	**0**	**1**	**2**	**4**	**8**	**11**	**14**	**15**	**29**
Number of blood samples	x1	First dose of phage	x3	x3	x3	x3	Last dose of phage	x1	x1

Patients who do not get any Phage Therapy through a drip in the vein, or by mouth, will have fewer blood tests. They will not have any blood tests on day 11, and on each day will only have a single set of blood samples taken.

Day	**0**	**1**	**2**	**4**	**8**	**14**	**15**	**29**
Number of blood samples	x1	First dose of phage	x1	x1	x1	Last dose of phage	x1	x1

Patients who have longer courses of Phage Therapy will continue to have blood tests to monitor their treatment every month. All blood samples will be collected by staff who have done lots of blood tests on children and young people, such as doctors, nurses or blood collectors.

Before starting Phage Therapy, at the end of the course and again 3 and 6 months after your treatment you will also be asked to complete an online questionnaire. This will ask you questions about your experience of the Phage Therapy and how it may have affected your quality of life. It will take 10 minutes to complete. Although we would like you to complete the entire questionnaire, you can skip any questions that you don't want to answer.



Most patients will be in the study for 1 month. This includes the 2 weeks of Phage Therapy and the follow-up visit 2 weeks after completing Phage Therapy. During this time, in addition to the tests described already, you will be asked about any symptoms and health events that may have occurred so that study doctors can work out how safe Phage Therapy is.

For some patients who are receiving longer courses of Phage Therapy, how long they are in the study will depend on how long Phage Therapy has been recommended for them. Once the Phage Therapy has finished, you will be followed up by your own doctor for at least 6 months. During this time, you will continue to receive invitations to complete the quality-of-life questionnaire at 3 and 6 months after your initial Phage Therapy treatment.

4 What do I have to do?

This research project has been designed to make sure the researchers interpret the results correctly and avoids study doctors or participants jumping to conclusions. It is important that the phage is given in the way it is written in the study protocol (study design) and all of the monitoring tests are done as written in the study protocol. It is also important that all of the information is collected accurately so that data from all patients in the study can be analysed together. This includes answers you give to the quality-of-life questionnaire. However, being part of this research will not affect you in other ways, such as what you can eat, any exercise or other activities you do, or other medications you may need. All of your other usual health care will continue as normal.

5 Other relevant information about the research project

This research is being conducted at many hospitals around Australia and will continue for 5 years. We would like to enrol 50-100 people in the study during this time. At *[Location where the research will be conducted]* we expect around 2-3 people to be enrolled each year. The research is a collaboration (teamwork) between multiple hospitals, universities and research institutes working together.

6 Do I have to take part in this research project?

Taking part in any research project is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you can stop taking part (withdraw) at any time. Your decision to take part or not, or to take part and then later stop taking part, will not affect your usual health care, your relationship with those treating you or your relationship with *[Institution]*.

7 What are the alternatives (other options) to taking part in this research?

You do not have to take part in this research project to receive treatment at this hospital. If you choose not to take part in this research, your doctor(s) may still decide to give you Phage Therapy but it may not be monitored in the way described in this research. This includes having

access to some of the special tests that are not available in usual hospital or community labs. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your own doctor and your parents or guardians.

8 What are the possible benefits of taking part?

We can't promise that you will receive any benefits from this research; however, possible benefits might be clearing your infection or improving how you feel. In addition, your treatment will be overseen and monitored by a group of study doctors which include specialists in infectious diseases and Phage Therapy from around Australia and the world. The information that we collect in this research will also help us and other researchers work out the best way to give Phage Therapy to other patients in the future. It may also help us make Phage Therapy more widely available in Australia to other patients.

9 What are the possible risks of taking part?

Any medical treatment can cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

The specific phage product you will get will be decided by your own doctor. This will be discussed with one of the study doctors, but this decision is not included in the research. Your doctor can give you information about the phage product you will get, including where it has come from and how it has been produced. Below is some general information about possible risks that might occur for patients receiving Phage Therapy.

Phage Therapy general information and risks
Phages are viruses that infect and kill bacteria, but they do not attack human cells. For this reason, phage therapy is very safe. It has been used for over 100 years to treat patients with bacterial infections. When phages are purified well, they cause very few side effects. Only phages that are highly purified will be used in this research.

Sometimes patients can have a brief reaction after the first few doses of phage. This is mostly due to the phage attacking and killing the bacteria causing your infection. It is usually a good sign that the phages are doing their job but it may be a little uncomfortable for you. You may have a fever or feel unwell in other ways (chills, headache, muscle aches). Depending on where your infection is, you may also get some pain there. Usually, this reaction only lasts a few hours and can be treated easily with simple medication like paracetamol or ibuprofen. Very occasionally, there may be a severe reaction which might mean that further doses of phage are delayed or not given.

Other side effects that might occur during your treatment include abnormalities in results of lab tests of your liver or kidneys, blood cells and immune system. If study doctors see any abnormalities on your blood tests, they will monitor them until they go back to normal for you. In our experience of treating patients in Australia, as well as reports from patients treated in other countries, these abnormalities in lab tests are usually not severe and all get better a few weeks after stopping the Phage Therapy.

Unknown risks of Phage Therapy
There might be other side effects that we do not expect or do not know about. Tell your study doctor immediately about any new or unusual symptoms that you get. Sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor might need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you. Any side effects that might occur during your treatment will

be managed or treated by the study doctors and your own doctors according to usual health care practice.

Risks of taking part in this research project
There are very few risks to taking part in this research because the study is mainly looking at how Phage Therapy should be given and monitored. As part of the research, you will be asked to give blood and other samples at specific timepoints, and the phage will be given to you at specific times of the day, for most patients injected through a drip in the vein. Having a treatment injected or blood samples taken might be uncomfortable and might cause bruising, minor infection or bleeding. If this happens, it can be easily treated.

If any problems happen for you because you are taking part in this research project, you should contact the study team as soon as possible. They will make sure you get the help and treatment you need. If you become upset at any time because you are taking part in this research, the study doctor will be able to get counselling or other support to help you.

10 What will happen to my test samples?

Most of the tests that will be done to monitor your treatment are the same lab tests that are usually used by doctors to monitor infections. These tests will be done at the usual labs where tests for patients from *[Location where the research will be conducted]* are done. Once the testing is finished, the samples will be destroyed in the same way as other patient samples are normally handled by labs.

Some of the tests are specific to the Phage Therapy, including tests to look for the levels of phage in your blood, tests to look at how your immune system is responding to the Phage Therapy and tests that will look at your microbiome (the collection of bacteria and other microorganisms, including viruses, which live in your body). Your blood and other samples such as urine, sputum, faeces (poo) that are collected for these tests may need to be sent to another lab in Australia that specialises in Phage Therapy. If this is the case, the samples will be sent in an anonymous way, using only a study code that will be given to you for the research project. None of your personal information (such as your name or address) will be sent outside of *[Location where the research will be conducted]*. Only study doctors from *[Location where the research will be conducted]* and your clinical team will know that these samples are yours, using your specific study code.

These tests are all needed for you to take part in the research. Once testing on these samples is finished, the samples will be kept in the outside lab in case more testing is required later for this research project. We will also ask your permission to use these stored samples in other similar research projects in the future, but this is optional. You can still take part in this research if you do not want to have your samples used in other projects. Any leftover samples will be destroyed 15 years after the end of the study in the usual safe way that human samples are destroyed and according to the law.

Some genetic tests that will be performed in this research will be:
1) to look at your microbiome which includes all of the bacteria, fungi and viruses (microorganisms) that normally live in our bodies, and how these might change during Phage Therapy. This test will not look at your genes, only at the genes of these microorganisms.
2) to look at the genes responsible for your immune system and how it responds to the Phage Therapy. This test will not look at any of your other genes. There is a small chance that we may find that your immune system is not responding as well to infections as in other people. If that happens, study doctors would let your doctor know so that they can discuss these with you and your parents or guardians.

11 What if new information comes up during this research project?

Sometimes, during a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue to take part in the research. If you decide you don't want to continue in the research, your study doctor will make sure your regular health care continues.

Also, on receiving new information, your study doctor might think it is better for you not to continue in the research project. If this happens, he/she will explain the reasons.

12 Can I have other treatments during this research project?

Taking part in this research project will not affect whether or not you can take other medications or treatments. But it is important to tell your study doctor and the study staff about any treatments or medications you are taking, including vitamins or herbal medicines. You should also tell your study doctor if any of your medications change during the time you are taking part in the research project.

13 What if I want to stop taking part in this research project?

If you decide to stop taking part in the research project, please let a member of the research team know so they can discuss with you anything that needs to happen or anything that you may need to do when you stop taking part in the research.

If you decide to stop taking part in the research project at any point, the study doctor and study staff will not collect any more information from or about you, although information already collected will be kept as part of the research to make sure that the results of the research can be measured properly.

14 Could this research project be stopped unexpectedly?

Although unlikely, this research project may be stopped unexpectedly for a variety of reasons, including unacceptable side effects or safety concerns.

15 What happens when the research project ends?

Once you have completed your course of Phage Therapy for your infection, you won't need any more Phage Therapy. If the infection comes back, gets worse or you get another infection that needs Phage Therapy again, your doctor can refer you to the study doctors again to see if you can be re-enrolled in the research project.

All other health care that you might need after the end of Phage Therapy will be according to usual practice and will be managed by your doctor.

When the project is completed in 5 years' time, the results of the research will be published in a scientific journal or may be presented at scientific meetings. A summary of publications and presentations will be made available for everyone on the Phage Australia website (https://criticalinfection.com/phage-australia/).

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By agreeing to take part in this research project you agree to let the study doctor and other study staff collect and use information about you for the research project. Any information that is collected as part of this research project that can identify you (like your name or address) will be kept confidential (private) and stored securely. Your information will only be used for this

research project and it will not be shared with anyone without your permission, except if it is required by law.

Information about you may be collected from your health records held at this and other health services (labs, clinics, hospitals) for this research (such as the results of lab tests or scans).

All study information will be entered into a web-based database called REDCap. This is provided by the University of Sydney and is protected so that only the study team can see the information. Within this database you will be given a study code. Your personal information will only be available to the team looking after you and the study team at *[Location where the research will be conducted]* so that they can discuss the best possible way to give you Phage Therapy, including any changes that might be needed in the dose of phage you are receiving. The rest of the research team would only be able to see non-personal information through your anonymous study code.

Any of your blood or other samples that need to be sent to outside labs will only have your study code and none of your personal information will be sent outside of *[Location where the research will be conducted]*. We expect to publish and/or present the results of this research project in scientific journals and meetings. In any publication and/or presentation, only anonymous information will be used so that you can't be identified, except with your permission.

Paper documents that have any of your personal information will be kept in locked cupboards in offices at *[Location where the research will be conducted]*. All research data will be stored for 15 years after the end of the project, and then everything with any personal information will be destroyed by permanently deleting electronic files and shredding any paper documents.

We will also ask your permission to use your anonymous information in other similar research projects in the future, but this is optional. You can still take part in this research if you do not want to have your information used in other projects.
According to the law in Australia and *[Name of state/territory]*, you are allowed to ask to see the information collected by the research team about you. You can also ask to have any information about you corrected if you disagree with it. Please contact the study team member named at the end of this Information Sheet if you would like to see your information.

17 Who is organising and funding the research?

Money for this research comes from the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF) of Australia. The research is being done by the Phage Australia Network of researchers (https://criticalinfection.com/phage-australia/), including *[Name of local PI and relevant study staff]*.

No member of the research team will get any money because you are taking part in this research project (other than their normal salary/wages).

18 Who has reviewed the research project?

All research in Australia involving humans is reviewed (checked) by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Sydney Children's Hospitals Network.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This has been developed to protect people who agree to take part in research projects.

19 Further information and who to contact

The person you need to contact will depend on what your question is.

If you want any more information about this project or if you have any medical problems which might be related to taking part in the project (for example, any side effects), you can contact the main study doctor *[Name of local PI]* on *[phone number]* or any of the following people:

Clinical (medical) contact person

Name	During normal working hours: *[Site PI name]* After hours or if unable to contact *[Site PI name]*: Infectious diseases registrar or consultant on call
Position	*[Title/position/department of Site PI]*
Telephone	During normal working hours: *[Site PI contact number]* After hours: Infectious diseases registrar or consultant on call via *[Hospital switch/on call Phone number]*
Email	*[Site PI Email address]*

If you have any complaints about the project or the way it is being done, or any questions about being part of a research project in general, you can contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Sydney Children's Hospital Network
HREC Executive Officer	Clare Bayram
Telephone	(02) 9845 3066
Email	SCHN-Ethics@health.nsw.gov.au